

K 02416

DEC 20 2002

510 (k) Summary

As Required by 21 section 807.92 (c)

1. **Submitter Name:** Siam Sempermed Corp., Ltd
2. **Address:** 110 Moo 8 Kanjanavanit Road. Pathong Hatyai Songkhla, Thailand 90230
3. **Phone:** (++66) 074 291 648
4. **Fax:** (++66) 074 291 650
5. **Contract Person:** Dr. Poonsuk Cherdkiatgumchai (Chief Quality Officer)
6. **Date summary prepared:** September 24, 2002
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 30798 US Hwy. 19N
Palm Harbor, USA, FL 34684
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E Harris
12. **Device Trade or Proprietary Name:** Non-sterile, powder-free latex examination gloves with polymer coating, vitamin E and protein claim (50 micrograms or less).
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Glove, Patient Examination, Latex
15. **Substantial Equivalency** is claimed against the following device :
Siam Sempermed Latex Patient Examination Glove, Powder free, 510(k) #k970794 (refer to Appendix 1 for FDA website printout.
This notification for the non-sterile, powder-free latex examination gloves with polymer coating, vitamin E, and protein claim (50 micrograms or less) is of the ABBREVIATED type as per the declaration of conformity on page 4 of this summary.
16. **Description of the Device:**
Non-sterile, powder-free latex examination gloves with polymer coating, vitamin E, and protein claim (50 micrograms or less).
17. **Intended use of the device:**
This device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.
18. **Safety and effectiveness of the device:**
This device is safe and effective as the predicate device *Siam Sempermed Latex Examination Glove, Powder free*. Indeed, it is equivalent
This is better expressed in the tabulated comparison (Paragraph 19 below)
19. **Summary comparing technological characteristics with other predicate device:**

General comparison result between non-sterile, powder-free latex examination gloves with polymer coating, vitamin E, and protein claim (50 micrograms or less) and predicate device (*Siam Sempermed Latex Examination Glove, Powder Free*) is tabulated below.

K02 4106

Technical comparison of specific elements is attached in the main submission.

FDA file reference number	510k number: k970794
Attachments inside notification submission file	REFER TO APPENDIX 1
TECHNOLOGICAL CHARACTERISTICS	<i>Comparison result</i> <u>REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION</u>
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (Not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2002

Siam Sempermed Corporation Limited
C/O Mr. Ned Devine, Jr.
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K024106

Trade/Device Name: Non-Sterile, Powder-Free Latex Examination Gloves with
Polymer Coating, Vitamin E and Protein Claim (50 Micrograms or Less)

Regulation Number: 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LYY

Dated: December 11, 2002

Received: December 13, 2002

Dear Mr. Devine

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

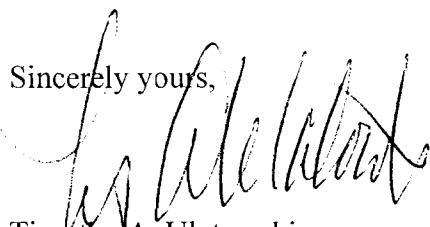
Page 2 – Mr. Devine

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Siam Sempermed Corp., Ltd.

510(k) Number: K024106

Device Name: Non-sterile, powder-free latex examination gloves with polymer coating, vitamin E, and protein claim (50 micrograms or less).

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

SPB for Clin
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024106